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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,134	01/23/2002	Jean-Claude Sonntag	4-31102A	2734

1095 7590 07/11/2003

THOMAS HOXIE
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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/11/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/048,134

Applicant(s)
Jean-Claude

Examiner
Gollamudi Kishore

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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DETAILED ACTION

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter (WO 98/24427 in combination with Lasic (Journal of Controlled Release, 1997) both are of record.

Hunter teaches that epothilones and Taxanes are microtubule disrupting agents and suggests the use of liposomes as carriers for these compounds (note page 8, lines 15-16), page 32, line 26 through 29). Instant invention therefore, is an obvious extension of Hunter's teachings. One of ordinary skill in the art would be motivated to use art well known liposomes as carriers for epothilones with a reasonable expectation of success.

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Lasic teaches various applications of liposomes because of their advantages as carriers. According to Lasic, encapsulation of toxic drugs in liposomes greatly reduces their toxic side effects. Lasic further teaches that since conventional liposomes are removed by reticuloendothelial system (RES), one can stabilize the liposomes using polyethylene glycol thereby increasing their blood circulation time (note the abstract, pages 204-208).

The use of liposomes as carriers for epothilones would have been obvious to one of ordinary skill in the art since such a use would reduce the toxicity of the drug as taught by Lasic. The use of PEG liposomes would have been obvious to one of ordinary skill in the art since PEG-liposomes have longer circulation time in the blood.

4. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter (WO 98/24427 of record by itself or in further combination with Lasic (Journal of Controlled Release, 1997) as set forth above, further in view of Boni (5,683,715) also of record.

The teachings of Hunter and Lasic have been discussed above. In essence, Hunter is suggestive of the use of liposomes as carriers for the microtubule disruptive agents such as Taxanes and epothilones and Lasic teaches the rationale for the use of liposomes and sterically stabilized liposomes. What is lacking in these references is the preparation of the composition in a dry form.

Boni discloses the liposomal formulations containing the microtubule disruptive agent, taxane. Boni teaches that bioactive molecules entrapped within the liposomes have

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enhanced therapeutic index and improved biodistribution and reduced toxicity. Boni further teaches that for storage, the liposomes can be dehydrated and reconstituted when desired (abstract, col. 5, line 26 through col. 6, line 48).

One of ordinary skill in the art would be further motivated to use liposomes as carriers for microtubule disrupting agents, epothilones, with a reasonable expectation of success, since the reference of Boni shows the effectiveness of the liposomes for the microtubule disruptive agent, taxane. The preparation of the composition in a dry state would have been obvious to one of ordinary skill in the art since in such a form it can be stored and reconstituted when desired as taught by Boni.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

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All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

July 10, 2003